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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,951	09/12/2003	William Ernest Pullman	29342/39617	8383

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EXAMINER

ANDERSON, JAMES D

ART UNIT PAPER NUMBER

1614

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/661,951

Applicant(s)

PULLMAN ET AL.

Examiner

James D. Anderson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 20-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 20-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed March 13, 2006, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Upon further consideration, Claims 4-6 were improperly rejected under 35 U.S.C. 102(b). As such, the rejection of Claims 4-6 under this statute is withdrawn.

Claims 1-3, 7-12, 20, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,140,329 for the reasons set forth in the Office Action dated December 9, 2005 and reiterated below.

The '329 patent discloses compositions comprising the instant compound in capsules or tablets containing "from 0.2-400 mg of active compound" (Column 3, Line 54). The reference provides specific examples of compositions comprising 50 mg of the instantly claimed compound (Column 8, Lines 30-65). To the extent that intended use

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determines patentability of a composition claim, the reference teaches the use of the instantly claimed compound for the treatment of erectile dysfunction and female sexual dysfunction (see especially Abstract, Claims, and Column 3, Lines 36-40).

Applicant's arguments have been fully considered but are not deemed to be persuasive. The main argument presented by Applicants with regard to this rejection is that the broad range of the '329 patent does not anticipate the narrow range instantly claimed. In support of this argument, Applicants have submitted a declaration under 37 C.F.R. 1.132 from Dr. Gregory Sides which claims that unexpected results were achieved using this narrow range (1 to 20 mg). In Applicant's arguments at Page 7, last paragraph:

"The surprising and unexpected results of the claimed invention is the criticality of a unit dosage composition of about 1 to about 20 mg of Compound (1), because this dosage range exhibits not only (i) low adverse side effects but also (ii) still being unexpectedly efficacious in treating sexual dysfunction."

Examiner has reviewed the Declaration of Dr. Sides as well as the Examples provided in Applicant's Specification but is not persuaded that unexpected results have been demonstrated. No criticality is seen in the dose range of 1 to 20 mg as instantly claimed. For example, Examiner notes that both adverse side effects and efficacy decrease as the dose is lowered from 25 to 2 mg (see pages 31-32 of Specification).

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This is neither unexpected nor surprising. The Declaration of Dr. Sides adds a data point for 20 mg in the adverse events Table but notably absent is the corresponding efficacy for the 20 mg dose. As such, the criticality of the 20 mg dose with regard to efficacy cannot be established. However, the table on page 31 of the Specification shows that no substantial difference in efficacy is seen in doses of 25, 50, and 100 mg. In addition, there is no statistically significant difference in the side effects observed between the 25 mg and 50 mg doses. However, efficacy and side effects both decrease as the dose is lowered from 25 to 2 mg.

Further, the pooled data from eight Phase 3 studies provided in the Declaration of Dr. Sides is unintentionally biased to doses of 5 mg, 10 mg, and 20 mg. The number of subjects used to compile the data for these data points (especially 20 mg) is much higher than that used for the comparative dose of 50 mg (635 subjects at 20 mg dose compared to 59 subjects at 50 mg dose). Note, for example, that the percentage of headaches reported in the placebo dropped by 50% when the number of subjects was 476 versus 134.

Thus, for the reasons set forth above, Examiner maintains that neither the current data nor Applicant's arguments demonstrate evidence of "surprising and unexpected results" using the instantly claimed range sufficient to overcome this rejection. The rejection of Claims 1-3 and 7-12 is **MAINTAINED**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-6, 21, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,140,329 (Issued October 31, 2000).

The '329 patent discloses compositions for the treatment of erectile dysfunction and female sexual dysfunction using the instantly claimed compound in tablets and capsules comprising from 0.2 to 400 mg active compound (Column 3, Lines 36-40; Column 3, Line 54; Examples; Claims). The reference provides specific examples of compositions comprising 50 mg of the instantly claimed compound (see especially Examples, Columns 8-10).

The instantly claimed doses of 2 mg, 2.5 mg, 5 mg, 10 mg, and 20 mg would have been *prima facie* obvious to one of ordinary skill at the time the invention was made. The doses claimed are within the range disclosed in the '329 patent and no evidence of unexpected results has been established in the present application. In the Examples provided on pages 31-32 of the instant application, Examiner notes that both efficacy and adverse side effects decrease when the dose is lowered from 25 to 2 mg. This is evidence of an obvious and expected result of the claimed doses. It is generally well known in the art that as one decreases the dose of a drug, side effects and efficacy will decrease.

The fact that a dose of 50 mg is exemplified in the examples of the '329 patent does not teach away from compositions comprising the lower doses recited in the range disclosed in the reference and one of ordinary skill in the art would appreciate that compositions comprising lower doses of the instant compound would lead to decreased efficacy and adverse side effects. Applicants have provided no evidence to contrary. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Thus, no unobviousness is seen in the compositions of Claims 4-6, 21, and 23 comprising the instantly claimed doses of 2 mg, 2.5 mg, 5 mg, 10 mg, and 20 mg.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

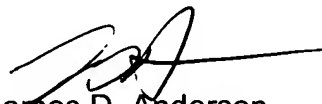
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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


James D. Anderson
Examiner
Art Unit 1614

May 22, 2006

 5/28/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER